GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE

RAJYA SABHA
UNSTARRED QUESTION NO.918
TO BE ANSWERED ON 03RD DECEMBER, 2024

SUSPENSION OF MANUFACTURING LICENSES OF LIPOSOMAL AMPHOTERICIN B INJECTION

918: SHRI RAJEEV SHUKLA:

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) whether CDSCO had on 11.03.2016 asked State Licensing Authorities to suspend manufacturing licenses of 10 manufacturers of "Liposomal Amphotericin B Injection" on safety and efficacy grounds and directed that it be regulated under Section 26A of Drugs and Cosmetics Act, 1940;

(b) whether licenses of these 10 manufacturers were suspended on 11.03.2016;

(c) whether "Liposomal Amphotericin B Injection" Monograph was omitted from Indian Pharmacopoeia" to forbid manufacture / sale of its generics in the country;

(d) whether, after 11.03.2016, several manufacturers are manufacturing / marketing it without trial under CTRI - INDIA; and

(e) if so, the steps taken in this regard?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SMT. ANUPRIYA PATEL)

(a) to (e): The Central Drugs Standard Control Organisation (CDSCO) on 11.03.2016 had requested the State Licensing Authorities concerned to suspend the licenses of 10 manufacturers of Liposomal Amphotericin B Injection in public interest. This was done after examination by an expert Committee of the data regarding the quality, safety and efficacy of Liposomal Amphotericin B Injection which was submitted by these manufacturers. The expert Committee had observed that the safety and efficacy of the products had not been established. Further, based on the recommendations of the committee, Liposomal Amphotericin B monograph was omitted from 7th edition of Indian Pharmacopoeia.

As per the action taken report received by CDSCO, State Licensing Authorities concerned have taken action against the manufacturers.

As per New Drugs Clinical trial Rules 2019, Novel Drug Delivery System like Liposomal drug products are always categorized as "New Drugs". Therefore, it is approved by CDSCO through the rigorous process of evaluation of submitted data and Subject expert committee (SEC) recommendation for safety and efficacy of the drugs.

Accordingly, the proposals of various firms for import/ manufacture and marketing of the product were received by CDSCO and same were deliberated on case to case basis, and the manufacturing and marketing permission were granted.

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